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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,717	04/13/2000	Katsuya Daimon	472552000100	7198

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/03/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/548,717

Applicant(s)

DAIMON ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-23 is/are pending in the application.
- 4a) Of the above claim(s) 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper No. 11) filed on April 12, 2002 has been entered.

Response to Arguments

2. Applicant's response to the office action (Paper No.11) is fully considered and deemed persuasive in part.
3. The rejection made under 35 U.S.C. 112 second paragraph in the previous office action is withdrawn herein in view of the applicants' amendment (Paper No.11).
4. With respect to the rejection made in the previous office action under 35 U.S.C. 102(e), Applicant's arguments with respect to claims 1-22 are considered but are moot in view of the new ground(s) of rejection based on the amendment.

New Grounds of Rejection necessitated by Amendment

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)".

Here, the new limitation of “ml/g” in the claim 1 appears to represent new matter. A careful review by examiner of the specification, this unit “ml/g” for pore volume is not present, infact the pore volume in the specification is recited as mm^3 / g . Thus the unit “ml/g” lacks descriptive support in the specification.

Since no basis has been found to support the new claim limitation in the specification, the claims are rejected as incorporating new matter.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, and 9-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uematsu et al. (USPN. 5,945,525). And in view of Yamauchi et al. (USPN. 6,274,387).

Uematsu et al. teach a method for isolating nucleic acids using silica-coated magnetic particles wherein Uematsu et al. disclose that the method comprises

(i) nucleic acid binding particulate carrier (silica coated magnetic particle) with a particle diameter of about 0.5 to about 15 μ m, a pore diameter of 0.1 to about 60nm, a pore volume of 0.01 to about 1.5ml/g and a specific surface area of about 100 to about 800 m²/g (see column 3, lines 44-65);

(ii) the magnetic silica particulate carrier contains superparamagnetic metal oxide (iron oxide) (see column 3, lines 44-47 and 53-54) and the metal oxide contained an amount of about 10 to about 60% by weight (see column 3, lines 56-58);

(iii) the method includes (a) mixing the material containing nucleic acids with the nucleic acid-binding particulate carrier so as to facilitate binding the nucleic acids to the particulate carrier; (b) separating a composite of the nucleic acids and the particulate carrier from the mixture in step (a) to remove contaminants; and eluting the nucleic acids from the composite of the nucleic acids and the particulate (see column 3, lines 66-67 and column 4, lines 1-11);

(iv) the material containing nucleic acids was a biological material containing DNA, RNA, protein etc., and the biological material include a bacteriophage, virus and bacteria (see column 7, lines 32-40);

(v) the method contains chaotropic substance selected from a group consisting of guanidine salt sodium iodide, potassium iodide, sodium (iso)thiocyanate, urea and the like (see column 7, lines 41-50);

(vi) wash buffer (first wash buffer) contains chaotropic substance (guanidine thiocyanate) and the elution buffer (second wash solution) contains alcohol (70%) (see column 8, lines 24-46);

(vii) the method further includes the detection of target nucleic acid comprising extracting the nucleic acids and amplifying the target nucleic acid by polymerase chain reaction (PCR) or nucleic acid sequence based amplification (NASBA) and detecting the target by nucleic acid hybridization assay (see column 8, lines 57-67 and column 9, lines 1-10). Although Uematsu et al. disclose that the particle pore diameter of 1-60 nm, Uematsu et al. did not teach the pore diameter of 80 to 250 nm.

Yamauchi et al. teach a method for extracting nucleic acids using particulate carrier, wherein the method comprises the particle average pore diameter ranging from 1 to 200 nm, more preferably 1 to 100 nm (see column 4, lines 22-30).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the method of extracting nucleic acids as taught by Uematsu et al. with the method as taught by Fraser et al. which is applicable to adsorb more nucleic acids because Uematsu et al. states that 'the specific surface and the pore volume depend on the size of surface pore diameter. The larger the surface pore diameter is, the larger the specific surface and the pore volume are. The larger the specific surface is, the larger the adsorbed amount of nucleic acid is' (see column 6, lines 5-11). One such alternative to increase the adsorption of nucleic acids, expressly motivated by Yamauchi et al. is to use proper pore diameter, surface diameter, and pore volume to achieve enhanced extraction or isolation of nucleic acids. An ordinary practitioner would have been motivated to combine the method of Uematsu et al. with the method of Yamauchi et

al. in order to achieve the expected advantage of a rapid and enhanced method for extraction or isolation of nucleic acids.

No claims are allowable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
June 27, 2002



JEFFREY FREDMAN
PRIMARY EXAMINER